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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/172,990	10/14/98	OZENBERGER	B AHP-98126-
			EXAMINER

HM12/0721
AMERICAN HOME PRODUCTS CORPORATION
PATENT LAW DEPARTMENT 2B2
ONE CAMPUS DRIVE
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CHECKER'S ART UNIT	PAPER NUMBER
1645	6

DATE MAILED: 07/21/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 5/10/99
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.
- A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-24 is/are pending in the application.
- Of the above, claim(s) 6-10 + 12-24 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-4 + 11 is/are rejected.
- ☒ Claim(s) 5 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-848.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-848
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-5 and 11 in Paper No. 5 is acknowledged.
2. Claims 6-10 and 12-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No.
3. Claim 5 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-4 encompass the genus of polynucleotides encoding all species and allelic variants of β -amyloid peptide-binding protein (BBP). The specification does not adequately describe the genus of nucleotide sequences encoding all BBPs because a representative number of species have not been described by complete structure (University of California v. Eli

Art Unit: 1645

Lilly, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)). Only two nucleotide sequences are described by complete structure (human and rat). The specification teaches "the high degree of specificity of the BBP1/BAP interaction in the Y2H assays since the substitution of three amino acids was sufficient to completely abrogate the association (Figure 7)" (page 38, lines 25-28).

Due to the high unpredictability in the molecular biology arts, the complete structure of any other encoding species of BPP is not adequately described such that one of skill in the art would conclude that Applicant had possession of what Applicant is claiming, i.e. a genus of encoding sequences for more than one species of BPP. Furthermore, a representative number of species have not been described by sufficient relevant identifying characteristics. The grounds of this rejection could be obviated by removing the clauses j and k from claim 1.

6. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term homologue does not have clear metes and bounds in the art, and it cannot be applied quantitatively to establish clear metes and bounds. See Lewin, page 1570.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. ("Adams"). Adams discloses sequence EST178050 which meets the limitations of clause 1 of

Serial Number: 09/172,990

4

Art Unit: 1645

claim 1 because "stringent conditions" (which would include very low stringency) would not exclude the sequence of Adams which shares 54.9% identity overall, and 98.1% best local identity, with instant SEQ ID NO:1. Because of the 98.1% best local identity, Adams meets the limitations of instant claim 11. Because the local identity is so high, the sequence of Adams would hybridize to the instant sequence or portion thereof and would inherently inhibit the expression of the BPP1 gene. It may be possible to obviate the grounds of this rejection by amending the claim to recite specific hybridization conditions that would exclude the sequence of Adams and by requiring that the antisense sequence is complementary to more than a portion of BBP1 sequence.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1645

11. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams in view of Gellissen et al. ("Gellissen"). The teachings of Adams are as set forth in ¶5 above. Adams does not teach expression or host cells. Gellissen teaches expression and host cells (abstract). It would have been obvious for one of ordinary skill in the art at the time the invention was made to express the polynucleotide of Adams using the expression system and host cells of Gellissen for the favourable characteristics taught by Gellissen (abstract).

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Thursday from 0730 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stephen Gucker

July 19, 1999



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